

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.

DATES: The meeting will be held on Thursday, March 10, 2022 from 11:00 a.m. until 4:30 p.m., and Friday, March 11, 2022, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP web site when this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted one week prior to the meeting at https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.

FOR FUTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway,

Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; e-mail address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Thursday, March 10, 2022, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with discussion of new draft recommendations on ethical and regulatory considerations for the use of artificial intelligence in human subjects research, followed by a presentation of draft recommendations on the risks for third parties involved in research, and finally draft recommendations for the Request for Information currently open for the National Institutes of Health's Genomic Data Sharing Policy. The second day, March 11, will

include consideration of the current HHS policy of engagement and the interpretation of

HHS support in 45 CFR 46, and continue discussion of topics from the first day's agenda.

Other topics may be added; for the full and updated meeting agenda, see

http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html. The meeting will

adjourn by 4:30 p.m. March 11th, 2022.

The public will have an opportunity to send comment to the SACHRP during the

meeting's public comment session or to submit written public comment in advance.

Individuals submitting written statements as public comment should submit their

comments to SACHRP at SACHRP@hhs.gov by midnight March 4th, 2022, ET.

Comments are limited to three minutes each.

Time will be allotted for public comment on both days. Note that public comment must

be relevant to topics currently being addressed by the SACHRP.

Dated: 01/31/2022

Julia G. Gorey

Executive Director, SACHRP

Office for Human Research Protections

[FR Doc. 2022-03370 Filed: 2/15/2022 8:45 am; Publication Date: 2/16/2022]